ABSTRACT

The present invention provides novel compositions of allosteric hemoglobin modifiers which are substantially free of impurities, specifically polymeric impurities. In one embodiment, the novel compositions contain an allosteric hemoglobin modifier compound and less than 100 ppm of the polymeric impurities generated during the preparation of this compound. Included in the present invention are novel methods for preparing allosteric hemoglobin modifiers that are substantially free of polymeric impurities. Also included in the present invention are improved methods for the purification of the product formed by the method of this invention. The novel methods of purification comprise extracting the crude composition with a water immiscible or partially immiscible solvent such as methylisobutyl ketone (MIBK) to lower amounts of impurities, specifically polymeric impurities. Also included are methods to reduce impurities by recrystallization of the crude synthesized product, followed by filtration of the recrystallized product. The present invention also includes the products made by the processes of the invention and methods for analyzing compositions comprised of these products.